

REMARKS

Claims 1 and 3-20 remain pending in the application. Claim 2 is being canceled, and its limitation being inserted into claim 1, to better present the subject matter of the invention. Applicants have no intention of abandoning any of their originally disclosed subject matter, and reserve the right to reinstate original claim 1 in this or a continuing application.

All of the claims were rejected, and the grounds for rejection are separately discussed below.

Rejection Under 35 U.S.C. § 102(b).

Claims 1-9 and 12-18 stand rejected under this statute, as being anticipated by European Patent Application Publication No. 0 094 116 A2 ("Close"). Close teaches analgesic compositions, such as those containing aspirin, that have enhanced dissolution in the intestinal tract. Specific compositions have: aspirin and excipients in a particle core; a coating over the core containing an active ingredient (e.g., additional aspirin) and an optional "dispersing aid," which assists in disrupting a coating in the environment of the intestines; and an outer enteric coating.

The Office Action contains erroneous information, and the rejection appears to have been based on this information. In particular, there is a statement that "The active core is taught as being selected from a plurality of active agents, all of which have some sensitivity to acid." Applicants cannot find any indication in the document that indicates acid sensitivity of the disclosed active agents, or that acid sensitivity was even considered to be relevant. In the case of aspirin and other nonsteroidal anti-inflammatory drug formulations, enteric coatings generally are applied not to protect the aspirin, but to protect the stomach against contact with the irritating drug. A discussion of this concept is attached, in the form of an article copyrighted in 2005 and titled "Uncovering the Benefits of Aspirin," and recently printed from the URL http://www.johnshopkinshealthalerts.com/reports/healthy_living/1530-1.html?type=pf.

Moreover, the Close document teaches combinations of additional active agent with the dispersing aid, in the coating. As these components are suspended in a coating composition, there must be some individual coating ingredient particles that are

in contact with the outer enteric coating material; inevitably, some of the aspirin in this coating will be in contact with an enteric coating layer. This would appear to make no difference for the product of Close, but is not a situation that would be desired for the products of the present application, which specify the presence of acid-sensitive active ingredients.

The teachings of Close do not include any use of acid-sensitive active ingredients and/or acid-sensitive excipients, and there can be no case for anticipation. This rejection should be withdrawn, upon reconsideration.

Rejection Under 35 U.S.C. § 103(a).

Claims 10, 11, 19, and 20 stand rejected under this statute, as being rendered obvious by a combination of teachings from the above-discussed Close document and U.S. Patent No. 6,391,342 ("Henriksen"). Henriksen discloses the use of a "separating" layer between a core that contains a benzimidazole compound having anti-ulcer activity and an outer enteric coating, that separating layer comprising a polymer, optionally also containing an auxiliary agent, or a melt "essentially consisting of one or more esters of glycerol and fatty acids" (column 8, third paragraph).

Henriksen does not contemplate the use of an alkaline substance in the disclosed formulations. This is apparent from a statement in column 5, at lines 38-40: "When this technique is used in accordance with the invention, there is no need to use any alkaline compounds or salts for further stabilization of the benzimidazole."

No meaningful combinations of teachings for the two applied documents, to produce the Applicants' invention, appear to be possible. Close is directed to compositions of drugs that are not acid-sensitive, its intermediate coatings are designed only to rapidly disintegrate upon reaching a higher-pH physiologic environment, and there is no apparent reason to substitute any acid-sensitive drug for its described active agents. Henriksen is directed to formulations of an acid-sensitive drug, but the formulations specifically do not contain an alkaline substance that stabilizes the drug, so substituting teachings of an alkaline substance from any source into this document would be in opposition to its plain teachings.

A suggested combination is an improper basis for an obviousness rejection when it would require a substantial reconstruction and redesign of the elements shown, and a change in the basic principles of operation. *In re Ratti*, 270 F.2d 1260, 123 USPQ 349 (CCPA 1959). In view of this legal standard, the combination proposed in the present rejection is not capable of establishing obviousness, and the rejection should be withdrawn upon reconsideration.

CONCLUSION

As discussed above, all of Applicants' claims 1 and 3-20 are both novel and unobvious over the cited documents. Accordingly, reconsideration, withdrawal of the rejections, and an early notice of allowability are respectfully requested.

If any minor matters remain to be resolved, please contact the undersigned to arrange for a telephonic or personal interview that could expedite resolution.

Respectfully submitted,

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